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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,706	09/24/2001	William E. Munger	044921-5029-01	4547

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WASHINGTON, DC 20004

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

10

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,706

Applicant(s)

MUNGER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method to screen or identify an agent which modulates BPH, classified in class 435, subclass 6. This Group is further subject to an election of species, as set forth below.
- II. Claims 8-12 and 51-52, drawn to a method to diagnose the onset or progression of BPH, classified in class 435, subclass 6.
- III. Claims 13-17, drawn to a method to differentiate BPH from prostate cancer, classified in class 435, subclass 6.
- IV. Claims 18-19, 22-24, 26, and 28-31, drawn to a set of oligonucleotide probes, and a solid support with a set of oligonucleotide probes attached, wherein each probe specifically hybridizes to a single gene, classified in class 536, subclass 24.31. This Group is further restricted to a single gene to which the probes hybridize, therefore if this Group is elected, applicant must elect a single gene from those listed in Tables 1-6. This is a RESTRICTION requirement.
- V. Claims 20-23, 25, and 27-31, drawn to a set of oligonucleotide probes, and a solid support with a set of oligonucleotide probes attached, wherein the set specifically hybridizes to multiple genes, classified in class 536, subclass 24.31.
- VI. Claims 32-38 and 53, drawn to a computer system comprising gene expression data, classified in class 700, subclass 90.

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- VII. Claims 39-43 and 54, drawn to a method of using a computer system to compare gene expression data, classified in class 702, subclass 20.
- VIII. Claims 44-48, drawn to a method for monitoring treatment of a patient with BPH, classified in class 435, subclass 6.
- IX. Claims 49-50, drawn to a computer readable storage medium comprising an algorithm for analyzing gene expression, classified in class 702, subclass 20.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and VII-VIII are not related. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods reciting different method steps and intended purposes. As the method of each Group recites different steps and is directed to a different intended result, the methods are each separate and distinct. In addition, the method of each Group may be preformed with knowledge of or reference to the steps or results of the method of any other Group. For these reasons, none of Groups I-III and VII-VIII are related.

None of Groups I-III and VII-VIII is related to either Group IV or Group V. None of the methods of Groups I-III or VII-VIII recites use of the probe sets of either of Groups IV or V, and neither of the products of Groups IV or V is limited to be a probe set for use in any of the methods of Groups I-III or VII-VIII. For these reasons, the products of Groups IV and V are not related to any of Groups I-III and VII-VIII.

None of Groups I-III and VIII is related to either of Groups VI or IX. None of the methods of Groups I-III or VIII is limited to be one performed on or with a computer system or program, such as the product of Groups VI and IX. Neither the computer product of Group VI nor the program on the medium of Group IX is limited to be one for use with or for any of the methods of Groups I-III and VIII. Further, both the computer system of Group VI and the medium comprising an program (algorithm) of Group IX may be used in a variety of methods, including comparing gene expression profiles in different animals. For these reasons, each of Groups VI and IX is separate and distinct from each of Groups I-III and VIII.

Neither of Groups IV or V are related to either of Groups VI or IX. The physical probe sets of Groups IV and V are not capable of being used in the computer system of Group VI nor in the program/algorithm on the medium of Group IX, therefore Groups IV and V are not related to either of Groups VI or IX.

Groups IV and V are separate and distinct. A set of probes wherein each probe hybridizes to a single gene, as in Group IV, necessarily comprises a different set of oligonucleotides (structures) than a set wherein the probes hybridize to a multiplicity of genes, as in Group V. As the products of Groups IV and V are limited to be different, each of Groups IV and V is directed to a different and distinct product. With regard to Group IV, a set of probes which specifically hybridizes to one gene is necessarily different from a set which specifically hybridizes to a different gene, therefore each set of probes specifically hybridizing to a single gene set forth in Tables 1-5 is a different and distinct product from a set of probes specifically hybridizing to any other gene. For

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this reason, every set represented by probes hybridizing to any single gene is a different invention, and Group IV is restricted to a single set of probes hybridizing to a single gene, and election of that gene is properly a restriction requirement.

Group IX is not related to either of Groups VI or VII. The computer system of Group VI is not limited to comprise the medium or program/algorithm of Group IX, and the medium/program of Group IX is not limited to be one for use in the system of Group VI. The method of Group VII does not recite use of the medium or program/algorithm of Group IX, and the medium/program of Group IX is not limited to be one for use in the method of Group IX. In addition, the product of Group IX may be used to analyze a variety of gene expression results, including genes not related to BPH. For these reasons, Group IX is separate and distinct from each of Groups VI and VII.

Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the computer system of Group VI may be used in a variety of methods, including comparison of gene expression profiles from different organisms.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, therefore restriction for examination purposes as indicated is proper.

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In addition, because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Election of Species

With regard to Group I, this application contains claims directed to the following patentably distinct species of the claimed invention: prostate cells from a BPH patient and various cell lines as set forth in Table 7.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e. a cell from a prostate patient or any ONE of the cell lines listed in Table 7) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5 and 7 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention (Group and gene or species) to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

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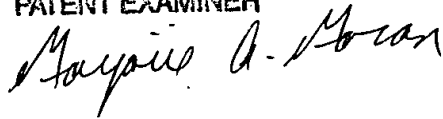
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308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

A handwritten signature in cursive script, appearing to read "Marjorie A. Moran", is written over the printed name and title.

mam
July 9, 2003